DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 200 and 800

[Docket No. 82N-0332]

Tamper-Resistant Packaging Requirements for Contact Lens Solutions and Tablets; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that established additional requirements for tamper-resistant packaging of contact lens solutions and tablets used to make those solutions. The rule was published in the Federal Register of November 5, 1982.

EFFECTIVE DATE: January 14, 1983.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, National Center for Devices and Radiological Health (HFK-140), Food and Drug Administration, 757 Georgia Ave., Silver Spring, MD 910, 301-427-7114.

SUPPLEMENTARY INFORMATION: In FR Doc. 82-30544 at page 50452 in the Federal Register of Friday, November 5, 1982, the following corrections are made:

1. On page 50452:

a. In column one in the third sentence of the summary, "opthalmic" is changed to "ophthalmic".

b. In column two in the second paragraph under "SUPPLEMENTARY INFORMATION", "opthalmic" is changed to "ophthalmic".

2. On page 50453:

a. In column two in the next-to-the-last sentence of the second full paragraph, "non-tamper resistant" is changed to "tamper-resistant."

b. In column three in the first sentence of the first full paragraph, "this effective date." is changed to "this retail level effective date."

3. On page 50454:

a. In column one in the next-to-the-last sentence in the first paragraph, "If a firm submits both a stay and an exemption" is changed to "If a firm submits both a petition for a stay and a petition for an exemption"; in the first sentence of the last paragraph, "found in sections 502(c), 515, and 701(a) of the act (21 U.S.C. 352(c), 360(e), and 371(a))." is changed to "found in sections 201(n), 502 (a) and (c), 515, and 701(a) of the act (21 U.S.C. 321(n), 352 (a) and (c), 360e(e), and 371(a)))." In the second sentence of the same paragraph, "Section 502(c) of the act deems" is changed to "As explained in the OTC drug document, the requirement for a label statement on the tamper-resistant feature of a product's packaging is authorized in part, by the misbranding provisions of sections 201(n) and 502(a), further, section 502(c) of the act deems."

4. On page 50455: In column one in the next-to-the-last sentence of the first paragraph, "regulatory analysis" is changed to "regulatory flexibility analysis". In the authority paragraph, "secs. 501, 502," is changed to "secs. 201(n), 501, 502," "52 Stat. 1049-1051" is changed to "52 Stat. 1041 as amended, 1049-1051" and "21 U.S.C. 351, 352," is changed to "21 U.S.C. 321(n), 351, 352,".

5. On page 50456 in § 800.12 *Contact lens solutions and tablets; tamper-resistant packaging:*

a. In the first sentence of paragraph (a), "and to the public health through the loss" is changed to "and with loss"; in the last sentence of paragraph (a), "or tablet for retail sale" is changed to "or tablet to be used to make such a solution for retail sale".

b. In paragraph (b) in the first sentence, "Each manufacturer or packer" is changed to "Each manufacturer and packer"; the third sentence is changed to read, "To prevent the substitution of a tamper-resistant feature after tampering, the indicator or barrier to entry is required to be distinctive by design or by the use of an identifying characteristic."; the last sentence is changed to read, "The tamper-resistant feature shall be designed to and shall remain intact when handled in a reasonable manner during manufacture, distribution, and retail display."

c. In paragraph (c) in the first sentence, "a product subject to paragraph (b) of this section" is changed to "a product covered by this section".

d. In paragraph (e) the last sentence is changed to read, "Any supplemental premarket approval application under this paragraph is required to include data sufficient to show that these changes do not adversely affect the product."

e. In paragraph (f):

(1) In the introductory text of the paragraph, "that the manufacturer" is changed to "that a product's manufacturer" and "a requirement" is changed to "a packaging or labeling requirement". (2) In paragraph (f)(1)(i) and (ii), "packaged on" is changed to "packaged for retail sale on".

(2) In paragraph (f)(2), "The requirements in paragraph (b) of this section for a distinctive indicator or barrier to entry and in" is changed to "The requirement in paragraph (b) of this section that the indicator or barrier to entry be distinctive by design and the requirement in"; and "and packaged on" is changed to "packaged for retail sale on".

(3) In paragraph (f)(3), "packaged before May 5, 1983." is changed to "packaged for retail sale before May 5, 1983."; and "Products packaged after May 5, 1983 must be" is changed to "Products packaged for retail sale after May 5, 1983, are required to be".

6. On page 50456, the authority statement at the bottom of column three is changed to read, "(Secs. 201(n), 501, 502, 515, 521, 701, 52 Stat. 1041 as amended, 1049-1051 as amended, 1055-1056 as amended, 90 Stat. 552-559, 574 (21 U.S.C. 321(n), 351, 352, 360e, 360k, 371).)"

Dated: January 6, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-1056 Filed 1-13-83; 8:45 am]

BILLING CODE 4160-01-M